REMARKS

The Examiner is thanked for the courteousness extended during the telephone interview of May 3, 2004. Claims 1-34 are pending in the present application. Claims 1, 13, 20, 22, and 31 are independent claims.

The drawings are objected to under 37 CFR 1.83(a). The objection is respectfully traversed. It is respectfully submitted that all of the elements recited in the pending claims are illustrated in the drawings as filed.

The objection proffers that "According to Applicant's amendment (and specification) the channels are formed from surface irregularities in the cover and substrate and also variations in the thickness of the reagent." See, page 5, second paragraph of the Office Action. It is noted that neither surface irregularities nor variations in thickness is required by any of the pending claims.

Further, the objection states that "The figures clearly show embossed and preformed channels". In that regard, the Examiner's attention is first directed to Figures 10-11. The cover and substrate illustrated in Figures 10-11 appear to be flat, devoid of any visible embossment or preformed channels. Moreover, the specification teaches at page 16 lines 6-12 that, "Opposite sides 370 of interior border cooperates with cover 312 and substrate 314 to define a capillary channel 340 extending between apertures 360, 362. Cover 312, substrate 314, and interior border 366 of sealed portion 36 define channel 340 . . . Channel 340 has a height similar to that of channel 40 as described above with reference to biosensor 10." Accordingly, it is submitted that the drawings as filed illustrate a non-embossed or non-preformed capillary channel.

The objection, however, focuses on Figures 2-5 and these figures will be address below. The objection states that Figures 3-5 show several different views of a uniform and symmetrical capillary channel 40 and gaps 62 and 64. See, Page 5, second paragraph of the Office Action. It is the case that the capillary channel 40 and gaps 62 and 64

illustrated in Figures 3-5 have generally uniform and symmetrical length and width. That is because the shape and size of the channel 40 and gaps 62 and 64 is not determined by luck, but rather by the predetermined placement of the sealed portion between the cover and the substrate. Specifically, as recited by the amended independent claims, the sides of the channel are defined by interior border of the sealed portion. For example, Figures 2-5 each illustrate a sealed portion 36 having an interior border 66.

Moreover, it is submitted that the drawings as submitted, including Figures 2-5, *do not* show embossed and preformed channels. The sealed and unsealed portions, as shown for example in Figures 2-3, are made to be distinct to more clearly illustrate to the reader of the specification that differences, although not always visible, indeed exist between the sealed and unsealed portions of the biosensor. At the time of filing, it was seen to be important to illustrate that, although not always visible, sealed and unsealed portions do in fact exist between the cover and the substrate.

In that regard, the specification states at page 4 lines 22-27 that, "Although sealed portion 36 and unsealed portions 37, 38 are clearly distinguishable from one another in the views of Figs. 2, and 3, it is appreciated that portions 36, 37, 38 will not always be visible to a user. For example, portions 36, 37, 38 may not be visible to a user when cover 12 is opaque. Portion 36 may, however, be visible to a user of biosensor 10 during use when cover 12 is transparent and the liquid sample being tested is colored."

Figure 1 further illustrates the non-embossed or non-preformed nature of the capillary channel 40. Figure 1 shows the generally flat configuration of both the cover and the substrate that will cooperate to form the channel. Figure 1 also illustrates the location of the reagent and the array relative to the cover and the substrate. As such, it is submitted that the drawings illustrate a capillary channel between a cover and substrate that is formed without the aid of a spacer or the additional manufacturing step of embossing either the cover or the substrate, as set forth in the specification as filed.

Still further, it is noted that Figures 4 and 5 are each *enlarged* cross-sectional views. See, page 2 lines 17-18 of the specification, *emphasis added.* In this regard, Figures 4 and 5 each illustrate a slight taper at the side of the channel. As the specification teaches that the channel is not pre-formed, it is appreciated that the angle of any such taper would not necessarily be uniform and dependent upon the location and/or thickness of reagent and even upon the existence of puckering of the cover, thus creating surface irregularities. As such, neither Figure 4 nor Figure 5 illustrate a pre-formed or embossed channel.

In light of the above, it is submitted that the non-embossed or non-preformed channels are clearly shown in the Figures. As such, reconsideration of the objection, leading to its withdrawal is respectfully requested.

Claims 1-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The independent claims have each been amended to clarify the structures that cooperate to define the biosensor. In addition, a Declaration from Brian S. Hill, a named inventor is submitted herewith.

Claims 1 and 13 have each been amended to recite that the sealed portion of the biosensor has an interior border and that the unsealed portion is positioned within the interior border of the sealed portion. These claims further recite a channel positioned between the cover and the substrate and having sides defined by the interior border. As such, Applicant relies on the cooperation of the claimed structure of the substrate and cover to create the channel.

Claim 20 has been amended to clarify the heating step. Specifically, the claim was amended to recite the step of heating portions of the thermoset adhesive to couple the bottom side to the substrate to define a sealed portion having an interior border and an unsealed portion positioned within the interior border, the unsealed portion cooperating with the substrate to define a capillary channel positioned between the cover and the substrate, having sides defined by the interior border and extending across the reagent.

Claims 22 and 31 have each been amended to recite that the sealed portion of the biosensor has an interior border and that the unsealed portion is positioned within the interior border of the sealed portion. These claims further recite a non-preformed channel positioned between the unsealed portion of the bottom side and the cover and having sides defined by the interior border. As such, Applicant relies on the cooperation of the claimed structure of the substrate and cover to create the channel.

In light of the above clarifying amendments, reconsideration of the rejections, leading to withdrawal of the rejection and allowance of the claims is respectfully requested.

Claims 1-9, 12, 13 and 16-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Hodges et al. (US 6,174,420 B1). The rejection is respectfully traversed. Hodges et al. discloses an electrochemical cell formed by a spacer sheet 1 having a circular hole 11 sandwiched between two sheets 12. See, Figures 12-14 of Hodges et al.

Claims 1 and 13 have each been amended to recite that the bottom side of the cover is sealed onto the substrate to define a sealed portion having an interior border and an unsealed portion positioned within the interior border of the sealed portion. Support for the amendment is found in the specification and drawings as originally filed and specifically at page 4 lines 1-3. No new matter is added by virtue of the amendments to the claims.

The rejection proffers that Hodges et al. discloses "a substrate, at least a portion being non-embossed (bottom element 13 in Figure 15) . . . and a cover (top element 13 in Figure 15)". Paper No. 13, Page 8. As stated above, claims 1 and 13 have each been amended to recite that the "bottom side of the cover is sealed onto the substrate". Further, claim 1 and 13 recite "a sealed portion having an interior border and an unsealed portion positioned within the interior border of the sealed portion". As discussed above, at most Hodges et al. discloses sheets 12 spaced apart from one another by at least one spacer sheet 1.

Accordingly, there is no description or suggestion in Hodges et al. of a biosensor that comprises "a substrate, at least a portion being non-embossed, a reagent positioned on the non-embossed portion of the substrate, and a cover positioned on the substrate, the cover including a top side and a generally flat non-embossed bottom side, the bottom side being sealed onto the substrate to define a sealed portion having an interior border and an unsealed portion positioned within the interior border of the sealed portion, at least a portion of the unsealed portion of the generally flat non-embossed bottom side cooperating with the substrate to define a channel positioned between the cover and the substrate, having sides defined by the interior border and extending across the reagent", as required by amended claim 1. Claims 2-9, and 12 depend from amended claim 1.

Likewise, Hodges et al. fails to disclose or suggest a biosensor that comprises "a substrate, at least a portion being non-embossed, a reagent positioned on the non-embossed portion of the substrate, and a cover positioned on the substrate, the cover having a top side and a generally flat non-embossed bottom side, and an opening extending between the top and bottom sides, the bottom side being sealed onto the substrate to define a sealed portion having an interior border and an unsealed portion positioned within the interior border, at least a portion of the unsealed portion of the generally flat non-embossed bottom side cooperating with the substrate to define a channel positioned between the cover and the substrate, having sides defined by the interior border and extending between the opening and the reagent", as required by amended claim 13. Claims 16-19 depend from amended claim 13.

Claims 1-9, 12, 13 and 16-19 are therefore not anticipated and are believed to be patentable over Hodges et al. Reconsideration leading to withdrawal of the rejection is respectfully requested.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hodges et al. (US 6,173,420 B1). Hodges et al. has been discussed above with reference to amended claim 1. As discussed above, there is no description or suggestion in Hodges et al. to one

skilled in the art to modify that reference to meet the limitations of amended claim 1. Claim 11 depends from amended claim 1.

It is respectfully contended that the differences between the claimed invention and the cited art are such that Applicants' invention as a whole would not have been obvious to one of ordinary skill in the art at the time the invention was made. It is respectfully contended that the claimed invention meets the test of patentability under 35 U.S.C. 103(a). Reconsideration of the rejection and allowance of the claim is respectfully requested.

The claims are believed to be in condition for allowance, and allowance of the application is respectfully requested. It is requested that this paper be considered a Petition for Extension of time sufficient to effect a timely response, and that all fees due be charged to Deposit Account Number 02-2958 with reference to (RDID 0030 US).

Respectfully submitted,
The Law Office of Jill L. Woodburn, L.L.C.

June 9, 2004
(Date)

Jill L. Woodburn
Registration No. 39,874

128 Shore Dr.
Ogden Dunes, IN 46368-1015
Telephone: 219-764-4005
Fax: 219-764-4070